DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 5, 2015

Intersection Medical, Inc.
c/o Mr. Warren Craycroft
Vice President of Regulatory and Quality
1808 Aston Ave Suite 120
Carlsbad, California 92008-7364

Re: K142503
Trade/Device Name: IMED-Z Fluid Status Monitor
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: DSB
Dated: April 30, 2015
Received: May 4, 2015

Dear Mr. Warren Craycroft,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

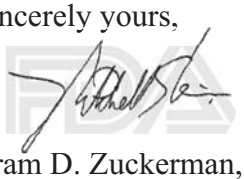
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K142503

Indications for Use Statement

510(k) Number K142503

Device Name: IMED-Z Fluid Status Monitor

Indications for Use:

The IMED-Z Fluid Status Monitor is intended for patients:

- With fluid management problems
- Taking diuretic medication
- Living with Heart Failure
- Living with End-stage Renal Disease
- Recovering from Coronary artery Disease related event
- Suffering from Recurrent Dehydration

This device is intended for use, under the direction of a physician, for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.

Prescription Use YES (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5. 510(K) SUMMARY

I. SUBMITTER

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Date Prepared: April 28, 2015

II. DEVICE

Name of Device:	IMED-Z Fluid Status Monitor
Common or Usual Name:	Fluid status monitor
Classification Name:	Impedance Plethysmograph (21CFR §870.2770)
Regulatory Class:	II
Product Code:	DSB

III. PREDICATE DEVICE

ZOE Fluid Status Monitor, K133301 (January 22, 2014)
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The IMED-Z Fluid Status Monitor is a non-invasive, battery-powered impedance monitor designed as an "early warning" monitor for determining changes in the fluid status of patients with fluid management problems.

The IMED-Z Fluid Status Monitor works by applying a low-amplitude, high frequency electrical current to the body and measuring the electrical impedance using

a four-point measurement technique through hydrogel (ECG style) electrode contacts. Base Impedance, also known as Zo, decreases when fluid increases and increases when fluid decreases.

The Fluid Status Monitor is designed for use with disposable, self-adhesive silver / silver chloride electrodes that are readily available from Intersection Medical, Inc. IMED-approved electrodes must be used with the IMED-Z Fluid Status Monitor. Zo reading obtained from unapproved electrodes may not be accurate.

The associated components and accessories include the following:

- IMED-Z acquisition module
- Battery pack and cable
- Battery charger
- Single-use electrode sensor
- Single-use electrode interface cables
- Single-use patient strap

V. INDICATIONS FOR USE

The IMED-Z Fluid Status Monitor has the identical indications for use as the predicate device ZOE Fluid Status Monitor K133301 (January 22, 2014):

The IMED-Z Fluid Status Monitor is intended for patients:

- With fluid management problems
- Taking diuretic medication
- Living with Heart Failure
- Living with End-stage Renal Disease
- Recovering from Coronary artery Disease related event
- Suffering from Recurrent Dehydration

This device is intended for use, under the direction of a physician, for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject and predicate devices are bioimpedance measurement devices that measure thoracic base impedance to assess fluid status. At a high level, the subject and predicate devices are based on the following same technological elements:

- 4-point impedance measurement of the patient's thorax
- Identical electric current output: 2.0 mA at 100 kHz
- Ag / AgCl hydrogel electrodes
- Type BF degree of protection
- Low-voltage monitor electronics; no mains voltage on-board either monitor

The following technological differences exist between the subject and predicate devices:

- Placement of electrodes: IMED-Z on back; predicate ZOE on chest
- The IMED-Z uses hardware to control measurement timing. The predicate ZOE uses a microprocessor and software.
- The IMED-Z is mounted on a patient strap with a short cable connection to the electrode sensor. The predicate ZOE is connected to the electrode by a 68 inch cable.

VII. PERFORMANCE TESTING:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing
The biocompatibility evaluation for the IMED-Z device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The electrode sensor and patient strap are classified as intact skin contact for a duration of less than 24 hours.

Electrical safety
Electrical safety testing in compliance with IEC 60601-1 Ed 3.1 was completed on April 27, 2015 by Intertek Testing Services NA Inc. The IMED-Z fulfils the requirements of IEC 60601-1. The Report Number is 101945161LAX-001.

Electromagnetic compatibility (EMC) testing
EMC testing to the IEC 60601-1-2 Ed 3.0 (2007-03) standard was completed on the IMED-Z device on July 28, 2014 by Intertek Testing Services NA Inc. The IMED-Z complies with the requirements of the standard indicated. The Report Number is 101754547BOX-001.

Design Verification and Validation Activities
Design Verification and validation activities have been performed on the IMED-Z. The IMED-Z meets its design specification requirements, including impedance measurement accuracy.

Shelf-life testing
Accelerated shelf-life testing has been completed, validating a shelf life of up to 24

months.

Usability testing
Usability testing was performed with healthcare workers to validate the human interface design and instructions for use to ensure safe and effective device interactions.

Performance bench testing
A head-to-head performance bench test with the predicate device was performed to characterize and compare the impedance measurement performance of the IMED-Z Fluid Status Monitor and the predicate ZOE Fluid Status Monitor (K133301). A calibrated precision resistor array was used to present a range of impedance loads to both devices. The IMED-Z device demonstrated substantial equivalence to the predicate ZOE device by matching measurement linearity and measurement accuracy of the ZOE device.

VIII. CONCLUSIONS

The biocompatibility testing, electrical safety evaluation, and EMC testing demonstrate that the IMED-Z device is as safe as the predicate ZOE Fluid Status Monitor. The hardware verification and validation demonstrate that design requirements, including measurement accuracy requirements, are met. The usability testing ensures that intended users can operate the device safely and effectively. The head-to-head performance bench testing demonstrates that the IMED-Z performs impedance measurements on simulated thoracic impedances as well as the predicate ZOE Fluid Status Monitor that is currently marketed for the same intended use.

Conclusions drawn from performance testing demonstrate that the IMED-Z device is as safe, as effective, and performs as well as the ZOE Fluid Status Monitor K133301, a legally marketed device.